

## REMARKS

### Rejection Under 35 USC §102(b)

The Examiner has maintained the rejection of Claims 1-5 and 13-18 under 35 USC §102(b) as anticipated by Webb et al. In summary, the reason given for maintaining the rejection is that despite the fact that Webb administers bcl-2 antisense for a 2-week course of treatment (i.e., a daily subcutaneous infusion of bcl-2 antisense oligonucleotide for two weeks), because a reduction in bcl-2 levels in the patients' lymph nodes was first observed after one week of the 2-week course of treatment the Examiner concludes that "treatment/therapy was observed in the first week." See page 6, lines 5-7 of the Office Action. On this basis, the 2-week course of treatment taught by Webb is redefined as "two cycles of therapy consisting of 7 days each." See page 5, line 19 of the Office Action.

The Examiner's attention is drawn to the second full paragraph of page 1138 of Webb, where it is taught that:

"...one 2-week course of treatment was given. Patients were followed up for 4 weeks after the end of treatment. If there was evidence of tumor response, a second course of treatment was given."

The Examiner's attention is further drawn to page 7, lines 1-6 of the specification, where Applicants provide the following definition:

"As used herein, the phrases "treating cancer" and "treatment of cancer" mean to inhibit the replication of cancer cells, inhibit the spread of cancer, decrease tumor size, lessen or reduce the number of cancerous cells in the body, or ameliorate or alleviate the symptoms of the disease caused by the cancer. The treatment is considered therapeutic if there is a decrease in mortality and/or morbidity, or a decrease in disease burden manifest by reduced numbers of malignant cells in the body."

Claims 1-5 and 13-18 of the application are directed to methods of treating cancer in a human. The Examiner's reliance on Webb's reductions in bcl-2 levels after one week of administration of bcl-2 antisense as evidence of "treatment/therapy" is misplaced, as reduction in

bcl-2 levels is not considered to be evidence of treatment of cancer, nor is it included in the definition of “treatment”. Reduction in bcl-2 levels does not indicate that the tumor has responded in any way that provides a benefit to the patient – it is merely a marker that indicates the antisense molecule has affected its target on the molecular level. It is important to note that, as set forth in the foregoing quote, Webb only evaluates the tumor response 4 weeks after bcl-2 antisense administration is completed. That is, treatment of cancer as claimed is observed by Webb only after completion of the full, daily, 2-week course of therapy. In contrast, Applicants claim a method for treating cancer in which a 2-13 day course of therapy is employed. Webb neither teaches nor suggests that anything less than 14 days of administration of bcl-2 antisense is effective to treat cancer, where tumor response or other patient benefit as defined by Applicants is observed. Webb therefore does not anticipate Claims 1-5 and 13-18 of the present application, and withdrawal of the rejection is requested.

#### Rejections Under 35 USC §103

The rejection of Claims 1-23 under 35 USC §103 is maintained for the same reasons as set forth in the rejection under §102. In view of the failure of Webb to teach or suggest treatment of cancer as defined in the specification with less than a 14-day administration of bcl-2 antisense, this rejection must also be withdrawn.

The rejection of Claims 29-33 under §103 that relies on Webb as the primary reference is also maintained. Again, in view of the failure of Webb to teach or suggest treatment of cancer as defined in the specification with less than a 14-day administration of bcl-2 antisense, this rejection must also be withdrawn.

#### Rejection Under 35 USC §112, Second Paragraph

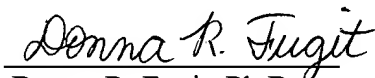
Claims 1 and 19 are presently amended to delete the second reference to “prevention” in each claim, overcoming the rejection for alleged indefiniteness. Withdrawal of the rejection is requested.

## CONCLUSION

Applicants respectfully submit that, in view of the foregoing amendments and remarks, the present application is in condition for allowance. If the Examiner would like to discuss any remaining issues in this application, Applicants would be pleased to have the opportunity for a personal interview.

Respectfully submitted,

BY:

  
Donna R. Fugit, Ph.D.  
Reg. No. 32,135

Genta, Inc.  
Two Connell Drive  
Berkeley Heights, NJ 07922  
Tel. (908) 219-3195  
Fax (908) 286-5982

Date: October 13, 2005